HHS Privacy Impact Assessment (PIA) Summary

FDA: FDA CBER Electronic Document Room

1

The following required questions represent the information necessary to complete the PIA Summary for transmission to the Office of Management and Budget. Note: If a question or its response is not applicable, please answer "No" to that question.

2 Summary of PIA Required Questions

	Question	Response
1	System:	FDA CBER Electronic Document Room
2	Is this a new PIA?	No
3	If this is an existing PIA, please provide a reason for revision:	Initial PIA Migration to ProSight
4	Date of this Submission:	Apr 25, 2006
5	OPDIV Name:	FDA
6	Unique Project Identifier (UPI) Number:	009-10-01-03-02-1020-00-204-079
7	Privacy Act System of Records (SOR) Number:	N/A
8	OMB Information Collection Approval Number:	???
9	Other Identifying Number(s):	???
10	System Name:	CBER Electonic Document Room (aka eSubmissions & Electronic Submissions Review Repository)
11	System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:	FDA Privacy Act Officer
12	Provide an overview of the system:	The Electronic Document Room (EDR) is a collection of systems that e-business enables the regulatory process for industry and CBER. The EDR stores, retrieves, and distributes electronic submissions to reviewers. The EDR is integrated with the CBER regulatory databases to allow for advanced searches based on data in the CBER databases. The EDR automates processing of submissions and automatically sends notifications to reviewers. The EDR also serves as a repository for CBER generated final documents.
13	Indicate if the system is new or an existing one being modified:	Existing
14	Does/Will the system collect, maintain (store), disseminate and/or pass through IIF within any database(s), record(s), file(s) or website(s) hosted by this system?	No
15	Is the system subject to the Privacy Act?	No
16	If the system shares or discloses IIF please specify with whom and for what purpose(s):	No IIF data
17	Describe in detail the information the agency will collect, maintain, or disseminate and why and for what purpose the agency will use the information:	The system Meta data about submissions that allows for searching of submissions such as submission dates, product name, corporate sponsor names, submission type, review office. The information is being used to allow users of the system to search for information or data in the system. Data collected is the data that the users of the system requested to be captured by the system. The information is being collected to allow users of the system to search for information or data in the system.
18	Describe the consent process:	No IIF data. Information is collected in an automated fashion from the regulatory databases or generated by the system it self.
19	Does the system host a website?	Yes
20	Does the website have any information or pages directed at children under the age of thirteen?	No
21	Are there policies or guidelines in place with regard to the retention and destruction of IIF?	Yes
22	Are there technical controls present?	Yes
23	Describe the IIF security controls:	Business owner approves account requests. Information is secured via an adapted industry standard authentication process and role-based privilege access method. FDA maintains the appropriate physical controls (electrical, A/C, restricted badge access, etc.) at the FDA Network Control Center.
24	Sr Official of Privacy Signature:	Kathleen D. Heuer
25	Sr Official of Privacy Signoff Date:	Jun 30, 2006

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

HHS Privacy Impact Assessment (PIA) Summary

FDA: FDA CBER RMS

1

The following required questions represent the information necessary to complete the PIA Summary for transmission to the Office of Management and Budget. Note: If a question or its response is not applicable, please answer "No" to that question.

2 Summary of PIA Required Questions

	Question	Response
1	System:	FDA CBER RMS
2	Is this a new PIA?	No
3	If this is an existing PIA, please provide a reason for revision:	Initial PIA Migration to ProSight
4	Date of this Submission:	Apr 25, 2006
5	OPDIV Name:	FDA
6	Unique Project Identifier (UPI) Number:	009-10-01-03-01-1020-00-204-079
7	Privacy Act System of Records (SOR) Number:	No
8	OMB Information Collection Approval Number:	No
9	Other Identifying Number(s):	No
10	System Name:	Regulatory Management System - Biologics Licensing Application (BLA)
11	System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:	FDA Privacy Act Officer
12	Provide an overview of the system:	RMS/BLA supports CBER's and CDER's Managed Review Process for the review and approval of applications for biological derived drugs and blood products (the BLAs) that are regulated by FDA. Submission Tracking Numbers (STNs) are assigned, information about BLAs, products, and facilities maintained and searchable, review milestone deadlines generated and reported, post-Approval commitments monitored and reported. IT solutions are essential in enabling FDA to meet its obligations under the statutes and PDUFA for the licensing of biologic products and facilities, the timely review of BLAs and tracking of post marketing commitments. RMS/BLA is integrated with DATS and EDR. Reviewers can open up electronic submissions from the EDR from within RMS/BLA. Under authority of 21CFR601, 21CFR820 (for IVD test kits), and the Prescription Drug User Fee Act and later amendments to the Act. BRMS is a legacy licensing system that was replaced by RMS-BLA in July 2000. GBRMS is an updated graphical interface to BRMS.
13	Indicate if the system is new or an existing one being modified:	Existing
14	Does/Will the system collect, maintain (store), disseminate and/or pass through IIF within any database(s), record(s), file(s) or website(s) hosted by this system?	No
15	Is the system subject to the Privacy Act?	No
16	If the system shares or discloses IIF please specify with whom and for what purpose(s):	No IIF data.
17	Describe in detail the information the agency will collect, maintain, or disseminate and why and for what purpose the agency will use the information:	Drug product and company names, product details such as indications, content, manufacturing facilities, manufacturing processes, FDA review committee member names, review status, licensed status, company and facility addresses, business phone # and business addresses of company representatives. FDA was established to regulate drugs and blood products in the US. It is responsible for the review and approval of Biologic License Applications (BLAs) under 21CFR600 and 601. It is required to track these BLA submissions, products, facilities, and review performance. The information that is captured and maintained in the RMS/BLA system is essential in allowing FDA to fulfill these obligations and report on its performance.

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

HHS Privacy Impact Assessment (PIA) Summary

FDA: FDA CBER RMS

18	Describe the consent process:	No IIF Data. All information in RMS/BLA was provided by the applicants (regulated drug companies) of BLA submissions. It is extracted from FDA Form 356H and from within the submissions itself. Other information is added to this from CBER generated actions such as the act of FDA licensing a product or issuing a letter or memo.
19	Does the system host a website?	No
20	Does the website have any information or pages directed at children under the age of thirteen?	No
21	Are there policies or guidelines in place with regard to the retention and destruction of IIF?	Yes
22	Are there technical controls present?	Yes
23	Describe the IIF security controls:	Business owner approves account requests. Information is secured via an adapted industry standard authentication process and role-based privilege access method. FDA maintains the appropriate physical controls (electrical, A/C, restricted badge access, etc.) at the FDA Network Control Center.
24	Sr Official of Privacy Signature:	Kathleen D. Heuer
25	Sr Official of Privacy Signoff Date:	Jun 30, 2006

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

HHS Privacy Impact Assessment (PIA) Summary

FDA: FDA CDER COMIS

1

The following required questions represent the information necessary to complete the PIA Summary for transmission to the Office of Management and Budget. Note: If a question or its response is not applicable, please answer "No" to that question.

2 Summary of PIA Required Questions

	Question	Response
1	System:	FDA CDER COMIS
2	Is this a new PIA?	No
3	If this is an existing PIA, please provide a reason for revision:	Initial PIA Migration to ProSight
4	Date of this Submission:	May 8, 2006
5	OPDIV Name:	FDA
6	Unique Project Identifier (UPI) Number:	009-10-01-04-02-0210-00-110-032
7	Privacy Act System of Records (SOR) Number:	09-10-0010
8	OMB Information Collection Approval Number:	N/A
9	Other Identifying Number(s):	N/A
10	System Name:	Center-wide Oracle Management Information System (COMIS)
11	System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:	FDA Privacy Act Officer
12	Provide an overview of the system:	Core COMIS is a Major Application that is used to track the status and progress of applications for Investigational New Drug Applications (IND), New Drug Applications (NDA), and Abbreviated New Drug Applications (ANDA), both pre- and post-marketing. The FD&C Act of 1938 authorizes this activity. The data is non-public information and it's strictly controlled. It contains no privacy information with the exception of the module known as the Bioresearch Monitoring Information System (BrmIS). This module contains identification of clinical investigators along with identifying information. The database is used to keep track of the investigators and link them to specific applications they are involved with. Because this database contains individual names of investigators and personal identifiers, access to it is more limited than any other Center system. BrMIS is exempt from PIA regulations because it contains investigatory records for law enforcement purposes.
13	Indicate if the system is new or an existing one being modified:	Existing
14	Does/Will the system collect, maintain (store), disseminate and/or pass through IIF within any database(s), record(s), file(s) or website(s) hosted by this system?	Yes
15	Is the system subject to the Privacy Act?	Yes
16	If the system shares or discloses IIF please specify with whom and for what purpose(s):	N/A
17	Describe in detail the information the agency will collect, maintain, or disseminate and why and for what purpose the agency will use the information:	Only BrmIS contains personal identifiers and is exempt under Title 21, vol 1, section 21.61(f). A specific exemption was provided because of the investigatory nature of the system.
18	Describe the consent process:	N/A
19	Does the system host a website?	Yes
20	Does the website have any information or pages directed at children under the age of thirteen?	No
21	Are there policies or guidelines in place with regard to the retention and destruction of IIF?	No
22	Are there technical controls present?	Yes
23	Describe the IIF security controls:	Administrative Controls: Clearly defined Policies and procedures to control access Technical: User ID, Passwords Physical Controls: Guards, Identification Badges.
24	Sr Official of Privacy Signature:	Kathleen D. Heuer
25	Sr Official of Privacy Signoff Date:	Jun 30, 2006

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

HHS Privacy Impact Assessment (PIA) Summary

FDA: FDA CDRH Image2000 Document Management (I2K)

1

The following required questions represent the information necessary to complete the PIA Summary for transmission to the Office of Management and Budget. Note: If a question or its response is not applicable, please answer "No" to that question.

2 Summary of PIA Required Questions

	Question	Response
1	System:	FDA CDRH Image2000 Document Management (I2K)
2	Is this a new PIA?	No
3	If this is an existing PIA, please provide a reason for revision:	Initial PIA Migration to ProSight
4	Date of this Submission:	Apr 25, 2006
5	OPDIV Name:	FDA
6	Unique Project Identifier (UPI) Number:	009-10-01-02-02-5030-00-110-246
7	Privacy Act System of Records (SOR) Number:	N/A
8	OMB Information Collection Approval Number:	No
9	Other Identifying Number(s):	No
10	System Name:	Center Electronic Submissions
11	System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:	FDA Privacy Act Officer
12	Provide an overview of the system:	Under the Medical Device Amendments of 1976, manufacturers of medical devices including but not limited to x-ray machines, pace makers and breast implants, are required to submit applications to the FDA for approval to ensure that these products are safe, effective, and labeled properly before they become available on the market. CDRH receives and reviews thousands of submissions from regulated industry and consumers seeking FDA approval to market new devices and products, as well as to track changes and adverse events related to approved products. These submissions traditionally have been scanned into the electronic document management system "Imae 2000". The CeSub project is based mostly upon the Image 2000 knowledge and document management system, and adds functionality to permit receipt and review of electronic submissions.
13	Indicate if the system is new or an existing one being modified:	Existing
14	Does/Will the system collect, maintain (store), disseminate and/or pass through IIF within any database(s), record(s), file(s) or website(s) hosted by this system?	No
15	Is the system subject to the Privacy Act?	No
16	If the system shares or discloses IIF please specify with whom and for what purpose(s):	The information contained within the CeSUB system is available only to FDA employees that obtain a CDRH user account. However, under the Freedom of Information Act, information contained within the CeSUB Image 2000 repository can be requested for review. These requests are obtained through the CDRH Office of Systems and Management which redacts any personal or proprietary information before sending a FOI-releasable copy of the submission to the requestor.
17	Describe in detail the information the agency will collect, maintain, or disseminate and why and for what purpose the agency will use the information:	Under the 1976 medical device amendments to the Food, Drug, and Cosmetic act, the Food and Drug Administration is mandated to collect and analyze manufacturer data related to the safety and efficacy of medical devices before they may be marketed in the US. The information contained in CeSub represents the official record of submissions from manufacturers. This includes Premarket Notifications 510(k), Premarket Approvals (PMAs), Investigational Device Exemptions (IDEs), labeling data, medical device reporting, and establishment registration and medical device listing forms. In addition, all FDA decision letters and any supplemental information requested from the manufacture are stored in the CeSUB Image 2000 repository. Any IIF data within the system pertains only to the manufacturer submitting the information, and not to patients.
18	Describe the consent process:	IIF, as defined within FDA, is not maintained on this system. Any information in identifiable format pertains only to the manufacturer or facility submitting the data.

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

HHS Privacy Impact Assessment (PIA) Summary

FDA: FDA CDRH Image2000 Document Management (I2K)

19	Does the system host a website?	No
20	Does the website have any information or pages directed at children under the age of thirteen?	No
21	Are there policies or guidelines in place with regard to the retention and destruction of IIF?	No
22	Are there technical controls present?	Yes
23	Describe the IIF security controls:	The CeSUB applications are located on the FDA/CDRH network and is only available to authorized FDA employees who must provide valid identification and be authenticated.
24	Sr Official of Privacy Signature:	Kathleen D. Heuer
25	Sr Official of Privacy Signoff Date:	Jun 30, 2006

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

HHS Privacy Impact Assessment (PIA) Summary

FDA: FDA CDRH Mammography Program Reporting Information System (MPRIS)

1

The following required questions represent the information necessary to complete the PIA Summary for transmission to the Office of Management and Budget. Note: If a question or its response is not applicable, please answer "No" to that question.

2 Summary of PIA Required Questions

	Question	Response
1	System:	FDA CDRH Mammography Program Reporting Information System (MPRIS)
2	Is this a new PIA?	No
3	If this is an existing PIA, please provide a reason for revision:	Initial PIA Migration to ProSight
4	Date of this Submission:	May 4, 2006
5	OPDIV Name:	FDA
6	Unique Project Identifier (UPI) Number:	009-10-01-02-02-4060-00-110-246
7	Privacy Act System of Records (SOR) Number:	09-10-0019
8	OMB Information Collection Approval Number:	0910-0309
9	Other Identifying Number(s):	No
10	System Name:	Mammography Program Reporting and Information System
11	System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:	FDA Privacy Act Officer
12	Provide an overview of the system:	Under the Mammography Quality Standards Act, all mammography facilities must be accredited by an approved accreditation body; certified by the FDA; inspected annually in order to legally provide mammography services in the United States; and facility medical personnel must meet qualification standards. MPRIS is used to schedule and hold reports of inspections, and provides inspection results to CMS.
13	Indicate if the system is new or an existing one being modified:	Existing
14	Does/Will the system collect, maintain (store), disseminate and/or pass through IIF within any database(s), record(s), file(s) or website(s) hosted by this system?	No
15	Is the system subject to the Privacy Act?	No
16	If the system shares or discloses IIF please specify with whom and for what purpose(s):	General information regarding the mammography facility, such as name, address, and telephone numbers, are public information, and may be released, in whole or in part, in response to a Freedom of Information Act (FOIA) request. In addition, data regarding certified facilities is published on the FDA web site for use by consumers in locating the mammography facilities nearest to them. Information regarding the specific manufacturers and models of mammography equipment in use at the facility is for FDA use only, and under Exemption 4 of the FOIA, that data is not releasable to the public. Under Exemption 7 of the FOIA, records regarding facility medical personnel who are under investigation for non-compliance with the provisions of the MQSA and 21 CFR Part 900, are not releasable except to other HHS Agencies, and to Federal law enforcement authorities.

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

HHS Privacy Impact Assessment (PIA) Summary

FDA: FDA CDRH Mammography Program Reporting Information System (MPRIS)

17	Describe in detail the information the agency will collect, maintain, or disseminate and why and for what purpose the agency will use the information:	The information collected identifies the name and physical location of the mammography facility, along with the facility mailing address, telephone and facsimile numbers, the types and number of mammography equipment in use, and the names and qualifications of facility medical personnel, including official contacts for accreditation, billing, and compliance matters. This information is not considered to be personal privacy information since it is required by, and solely used in keeping with, the provisions of the MQSA and 21 CFR Part 900, that is, in order to contact the regulated facility regarding FDA matters, to determine their certification status, to schedule inspections, and to determine the compliance of the facility and facility personnel with MQSA law and regulations. The System of Records: 09-10-0019, "Mammography Quality Standards Act (MQSA) Inspector Profile System, HHS/FDA/CDRH" (formerly the "Mammography Quality Standards Act (MQSA) Training Records") is no longer in use at FDA, and all computerized records that this system was used to collect have been purged from the system. The responsibilities for MQSA inspector audits, evaluations of the inspector's field performance, and inspector continuing education, have been transferred to the Division of State-Federal Relations, in the FDA Office of Regulatory Affairs. The only information collected by the DMQRP regarding MQSA-certified inspectors is their name, office address, and office telephone and facsimile numbers. This is the minimum information about the inspectors necessary to provide them technical, equipment, and policy guidance support.
18	Describe the consent process:	Collection of information from facilities is performed by FDA-approved accreditation bodies, and by FDA inspectors, or State inspectors working under contract to FDA, during mandatory annual inspections. The information collected, and the purposes for the information collection, are detailed in the MQSA and in 21 CFR Part 900. Further information regarding data collection and purposes are published in policy guidance documents, and posted on the FDA web site, for use by regulated industry, practitioners, and the public. Information collected regarding State inspectors working under contract to FDA is obtained from State authorities at the time of contract signing, and it is limited to publicly-available information, such as name, office address, and office telephone number. This information is provided in order for FDA to contact, when necessary, certified MQSA inspectors.
19	Does the system host a website?	Yes
20	Does the website have any information or pages directed at children under the age of thirteen?	No
21	Are there policies or guidelines in place with regard to the retention and destruction of IIF?	No
22	Are there technical controls present?	Yes
23	Describe the IIF security controls:	No IIF is maintained on this system.
24	Sr Official of Privacy Signature:	Kathleen D. Heuer
25	Sr Official of Privacy Signoff Date:	Jun 30, 2006

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

HHS Privacy Impact Assessment (PIA) Summary

FDA: FDA CFSAN Food Additives Regulatory Management (FARM)

1

The following required questions represent the information necessary to complete the PIA Summary for transmission to the Office of Management and Budget. Note: If a question or its response is not applicable, please answer "No" to that question.

2 Summary of PIA Required Questions

	Question	Response
1	System:	FDA CFSAN Food Additives Regulatory Management (FARM)
2	Is this a new PIA?	Yes
3	If this is an existing PIA, please provide a reason for revision:	Initial PIA Migration to ProSight
4	Date of this Submission:	May 3, 2006
5	OPDIV Name:	FDA
6	Unique Project Identifier (UPI) Number:	009-10-01-02-02-4050-00-110-246
7	Privacy Act System of Records (SOR) Number:	N/A
8	OMB Information Collection Approval Number:	None
9	Other Identifying Number(s):	None
10	System Name:	Food Additives Regulatory Management (FARM)
11	System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:	FDA Privacy Act Officer
12	Provide an overview of the system:	The FARM Project's electronic information management system is designed to support the electronic processing, review, maintenance, and reporting for food ingredient submissions. This includes the management of food and color additive petitions, Food Contact Notifications (FCNs), Generally Recognized as Safe Notices (GRNs) and Biotechnology Consultations (BNFs), by providing modern electronic information management tools necessary for the food ingredient reviewers and managers to maximize their productivity. FARM allows reviewers to spend more time reviewing submissions, since they spend less time searching for, processing, and sharing information. FARM also allows reviewers to utilize state-of-the art analytical and search tools to support safety reviews, evaluations, and decisions. FARM is currently able to support industry electronic submission of food ingredient submissions and correspondence in a consistent/standard electronic format further improving efficiencies for industry and the FDA. Freedom of Information (FOI) requests and other communications disclosing information to industry and consumers are done electronically through the FARM System The FARM system provides: Efficient desktop information retrieval and processing Workload management Step-by-step tracking capability for all aspects of the submission and review processes Analytical tools on the desktop to link all information pertinent to the review Expanded capability to access online scientific databases Capability to capture the data necessary to compare performance of base-line system, established in FY 2001, against performance levels/metrics of the previous five years.
13	Indicate if the system is new or an existing one being modified:	Existing
14	Does/Will the system collect, maintain (store), disseminate and/or pass through IIF within any database(s), record(s), file(s) or website(s) hosted by this system?	No
15	Is the system subject to the Privacy Act?	No
16	If the system shares or discloses IIF please specify with whom and for what purpose(s):	N/A

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

HHS Privacy Impact Assessment (PIA) Summary

FDA: FDA CFSAN Food Additives Regulatory Management (FARM)

17	Describe in detail the information the agency will collect, maintain, or disseminate and why and for what purpose the agency will use the information:	The FARM System collects information from the food industry on ingredients that are added to or will come in contact with food for human consumption. The information that industry submits to the agency contains chemistry, toxicology, environmental, nutritional, microbiological, and other relevant data. Information collected by the FARM System consists of data required to perform the safety review of food ingredients under the Federal Food Drug and Cosmetic Act and Regulations in Part 21 CFR Sections 71 & 170-190. These regulatory documents describe the data required from industry for the Food Contact Notification (FCN), Generally Recognized as Safe Notice (GRN), and Bioengineered Foods Consultation (BNF) processes. All notices and notifications must contain appropriate and sufficient scientific data and information to support the safety review process. The agency collects only the information provided for under the Federal Food, Drug and Cosmetic Act and in the corresponding regulations in 21 CFR 71-199.
18	Describe the consent process:	N/A
19	Does the system host a website?	No
20	Does the website have any information or pages directed at children under the age of thirteen?	No
21	Are there policies or guidelines in place with regard to the retention and destruction of IIF?	Yes
22	Are there technical controls present?	No
23	Describe the IIF security controls:	Policies and procedures
24	Sr Official of Privacy Signature:	Kathleen D. Heuer
25	Sr Official of Privacy Signoff Date:	Jun 30, 2006

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

HHS Privacy Impact Assessment (PIA) Summary

FDA: FDA OC Administrative Systems Automation Project (EASE)

1

The following required questions represent the information necessary to complete the PIA Summary for transmission to the Office of Management and Budget. Note: If a question or its response is not applicable, please answer "No" to that question.

2 Summary of PIA Required Questions

	Question	Response
1	System:	FDA OC Administrative Systems Automation Project (EASE)
2	Is this a new PIA?	No
3	If this is an existing PIA, please provide a reason for revision:	Initial PIA Migration to ProSight
4	Date of this Submission:	Nov 19, 2003
5	OPDIV Name:	FDA
6	Unique Project Identifier (UPI) Number:	009-10-01-10-01-1020-00-403-131
7	Privacy Act System of Records (SOR) Number:	09-40-0010, 09-90-0018, 09-40-0001, 09-90-0017, 09-90-0001
8	OMB Information Collection Approval Number:	N/A
9	Other Identifying Number(s):	N/A
10	System Name:	Enterprise Administrative Support Environment (EASE)
11	System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:	FDA Privacy Act Officer
12	Provide an overview of the system:	EASE is an FDA-wide administrative system that provides essential personnel, organization and locator information, automates time and attendance, and provides ad hoc reporting though its associated RAM data warehouse.
13	Indicate if the system is new or an existing one being modified:	Existing
14	Does/Will the system collect, maintain (store), disseminate and/or pass through IIF within any database(s), record(s), file(s) or website(s) hosted by this system?	Yes
15	Is the system subject to the Privacy Act?	Yes
16	If the system shares or discloses IIF please specify with whom and for what purpose(s):	HHS is provided FDA civilian time and attendance data on a biweekly basis to process FDA payroll. Location data is provided to HHS for the HHS Employee Location System.
17	Describe in detail the information the agency will collect, maintain, or disseminate and why and for what purpose the agency will use the information:	FDA personnel data is retrieved from DHHS Personnel Files (FDA only) for the purpose of providing corporate data to various FDA Systems, to provide management reports and to provide the basis to process civilian personnel time and attendance recording. Person location data is collected to provide HHS and FDA with location and email directories. FDA Non employee personnel data is collected to provide a basis for location and security purposes. Only those data elements required for the FDA applications is being maintained.
18	Describe the consent process:	HHS collects the Personnel Data. The Center Representatives, and the various roles involved with the specific data provide notification to the employees/non-employees upon request of the data. Information about the collection of data is providing within the users manuals and upon training.
19	Does the system host a website?	Yes
20	Does the website have any information or pages directed at children under the age of thirteen?	No
21	Are there policies or guidelines in place with regard to the retention and destruction of IIF?	No
22	Are there technical controls present?	Yes
23	Describe the IIF security controls:	System security is based on Database and Application Roles, Organization and Data Element Access. The System is accessed only within the FDA Firewall via ID/Password.
24	Sr Official of Privacy Signature:	Kathleen D. Heuer
25	Sr Official of Privacy Signoff Date:	Jun 30, 2006

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

HHS Privacy Impact Assessment (PIA) Summary

FDA: FDA OC Agency Information Management System (AIMS)

1

The following required questions represent the information necessary to complete the PIA Summary for transmission to the Office of Management and Budget. Note: If a question or its response is not applicable, please answer "No" to that question.

2 Summary of PIA Required Questions

	Question	Response
1	System:	FDA OC Agency Information Management System (AIMS)
2	Is this a new PIA?	No
3	If this is an existing PIA, please provide a reason for revision:	Initial PIA Migration to ProSight
4	Date of this Submission:	Nov 19, 2003
5	OPDIV Name:	FDA
6	Unique Project Identifier (UPI) Number:	009-10-01-10-01-1010-00-404-142
7	Privacy Act System of Records (SOR) Number:	09-10-0004 (FDA) Communications (Oral & Written) with the Public, 09-90-0058 (HHS) FOI Case Files and Correspondence Control Index, OGE-1 (Office of Government Ethics) Financial Disclosure Reports & Other Ethics Programs, OGE-2 (Office of Government Ethics) Confidential Statements of Employment & Financial Interest, 09-90-0008 Conflict of Interest Records, HHS/OS/ASPER, OPM/Central-9 Personnel Investigations Records
8	OMB Information Collection Approval Number:	N/A
9	Other Identifying Number(s):	N/A
10	System Name:	Agency Information Management System (AIMS)
11	System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:	FDA Privacy Act Officer
12	Provide an overview of the system:	AIMS provides administrative tracking and electronic storage for several agency functions. The core data within AIMS is pulled from the agency ASAP system for staff, contractor and organizational data required for the applications. The core also contains any information that is shared by two or more of the AIMS modules. The modules are Correspondence (both internal generated and received from external sources), Freedom of Information (FOI), Federal Register (FR), Dockets Management, Advisory Committee, Ethics, Security Clearances and Interagency Consult Reviews. The system also has a records management application for all records tracked in the system. The module for Administrative Tracking and Electronic Document Storage of FOI requests, responses, and related correspondence is authorized by the Freedom of Information Act, (FOIA) 5 U.S.C. 552. The module for Ethics records is authorized by the Ethics in Government Act (PL 95-521) and the Ethics Reform Act of 1989, as amended (PL 101-194). The Civil Service Act authorizes the module for Security Clearances. The Federal Advisory Committee Act authorizes the module for Advisory Committee Records.
13	Indicate if the system is new or an existing one being modified:	Existing
14	Does/Will the system collect, maintain (store), disseminate and/or pass through IIF within any database(s), record(s), file(s) or website(s) hosted by this system?	Yes
15	Is the system subject to the Privacy Act?	Yes
16	If the system shares or discloses IIF please specify with whom and for what purpose(s):	The only application that shares data with external sources is Security Clearances. The security clearance process goes through OMB. FOIA module information is shared with agency employees involved in the processing of FOIA requests. Certain information is available to the public as provided by the FOIA.
17	Describe in detail the information the agency will collect, maintain, or disseminate and why and for what purpose the agency will use the information:	FDA receives approximately 24,000 FOI request per year. A tracking system is required to monitor the processing of requests. In addition the FOIA and the Ethics in Government Act have annual reporting requirements that are based on information collected in the system. The Security Clearance staff is responsible for maintaining the security levels for all FDA personnel and its contractors and must have a system for tracking security clearances.

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

HHS Privacy Impact Assessment (PIA) Summary

FDA: FDA OC Agency Information Management System (AIMS)

18	Describe the consent process:	Information is obtained from correspondence submitted by the FOI requesters and individuals that correspond with the agency or comment on a Federal Register notice. FDA's Public Information Regulations at 21 CFR Part 20 inform the public of the procedures for submitting FOI requests. Federal Register notices inform individuals of the procedures for commenting on a notice. In the case of security clearances and ethics, when an individual comes to work at FDA as an employee or contractor they are required to complete forms requesting the information. Forms contain notification statements informing the individuals of the purpose for collecting the information and the authority for collecting the information.
19	Does the system host a website?	No
20	Does the website have any information or pages directed at children under the age of thirteen?	No
21	Are there policies or guidelines in place with regard to the retention and destruction of IIF?	No
22	Are there technical controls present?	Yes
23	Describe the IIF security controls:	All data is stored on secure servers within the FDA operating infrastructure. All access is through user names and passwords that follow all HHS and FDA Security guidelines.
24	Sr Official of Privacy Signature:	Kathleen D. Heuer
25	Sr Official of Privacy Signoff Date:	Jun 30, 2006

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

HHS Privacy Impact Assessment (PIA) Summary

FDA: FDA OC Emergency Operations Network Project (EON)

1

The following required questions represent the information necessary to complete the PIA Summary for transmission to the Office of Management and Budget. Note: If a question or its response is not applicable, please answer "No" to that question.

2 Summary of PIA Required Questions

	Question	Response
1	System:	FDA OC Emergency Operations Network Project (EON)
2	Is this a new PIA?	No
3	If this is an existing PIA, please provide a reason for revision:	Initial PIA Migration to ProSight
4	Date of this Submission:	Aug 18, 2004
5	OPDIV Name:	FDA
6	Unique Project Identifier (UPI) Number:	009-10-01-08-01-0305-00-104-010
7	Privacy Act System of Records (SOR) Number:	N/A
8	OMB Information Collection Approval Number:	N/A
9	Other Identifying Number(s):	N/A
10	System Name:	Emergency Operations Network (EON)
11	System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:	FDA Privacy Act Officer
12	Provide an overview of the system:	The Emergency Operations Network (EON) provides an Agency-wide system to fully support the enterprise for the full range of FDA emergencies through the implementation of two robust infrastructures, functional and technological, and the reengineering of the present emergency system. The development and incorporation of agency-wide guidance in the EON will ensure that the Agency response is uniform, consistent, and coordinated. EON will contain contact information for key FDA staff members, including home addresses, telephone numbers and email addresses. This data is needed to effectively and efficiently respond to evolving emergency situations. The authorizing legislation for EON includes the Food Drug & Cosmetic Act 903(b) and 711, the Bioterrorism Act (2002), and Homeland Security Presidential Directives.
13	Indicate if the system is new or an existing one being modified:	Existing
14	Does/Will the system collect, maintain (store), disseminate and/or pass through IIF within any database(s), record(s), file(s) or website(s) hosted by this system?	No
15	Is the system subject to the Privacy Act?	No
16	If the system shares or discloses IIF please specify with whom and for what purpose(s):	N/A
17	Describe in detail the information the agency will collect, maintain, or disseminate and why and for what purpose the agency will use the information:	The EON project is in the development phase. EON will provide FDA contact data extracted from the publicly available DHHS employee directory website. For selected key individuals, this will be augmented with other contact information (home and other personal telephone numbers and email addresses) extracted from the FDA Redbook.
18	Describe the consent process:	N/A
19	Does the system host a website?	No
20	Does the website have any information or pages directed at children under the age of thirteen?	No
21	Are there policies or guidelines in place with regard to the retention and destruction of IIF?	No
22	Are there technical controls present?	No
23	Describe the IIF security controls:	N/A
24	Sr Official of Privacy Signature:	Kathleen D. Heuer
25	Sr Official of Privacy Signoff Date:	Jun 30, 2006

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

HHS Privacy Impact Assessment (PIA) Summary

FDA: FDA OC FDA Consolidated Infrastructure

1

The following required questions represent the information necessary to complete the PIA Summary for transmission to the Office of Management and Budget. Note: If a question or its response is not applicable, please answer "No" to that question.

2 Summary of PIA Required Questions

	Question	Response
1	System:	FDA OC FDA Consolidated Infrastructure
2	Is this a new PIA?	No
3	If this is an existing PIA, please provide a reason for revision:	Initial PIA Migration to ProSight
4	Date of this Submission:	Nov 19, 2003
5	OPDIV Name:	FDA
6	Unique Project Identifier (UPI) Number:	009-10-02-01-01-0301-00-404-139
7	Privacy Act System of Records (SOR) Number:	n/a
8	OMB Information Collection Approval Number:	n/a
9	Other Identifying Number(s):	n/a
10	System Name:	FDA OC Consolidated Infrastructure
11	System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:	FDA Privacy Act Officer
12	Provide an overview of the system:	FDA is moving towards long-term improvements in the structuring of IT services across centers aimed at facilitating greater integration in the delivery of programs and realizing significant cost savings. Efficiencies will be realized by consolidating the technology infrastructure services and standardizing on how IT service is provided. The consolidated infrastructure is described as local area networks, help desk and call center, email, voice and data services, desktop management and support, database and server management, and Internet/Intranet services.
13	Indicate if the system is new or an existing one being modified:	Existing
14	Does/Will the system collect, maintain (store), disseminate and/or pass through IIF within any database(s), record(s), file(s) or website(s) hosted by this system?	No
15	Is the system subject to the Privacy Act?	No
16	If the system shares or discloses IIF please specify with whom and for what purpose(s):	n/a
17	Describe in detail the information the agency will collect, maintain, or disseminate and why and for what purpose the agency will use the information:	FDA is collecting data for administration and e-mail purposes from and for the employees and contractors in the agency. External data is collected through e-mail from the FDA public website. No PII information is requested, but the public user may have chosen to furnish it.
18	Describe the consent process:	n/a
19	Does the system host a website?	No
20	Does the website have any information or pages directed at children under the age of thirteen?	No
21	Are there policies or guidelines in place with regard to the retention and destruction of IIF?	No
22	Are there technical controls present?	No
23	Describe the IIF security controls:	n/a
24	Sr Official of Privacy Signature:	Kathleen D. Heuer
25	Sr Official of Privacy Signoff Date:	Jun 30, 2006

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

HHS Privacy Impact Assessment (PIA) Summary

FDA: FDA OC FDA Unified Registration and Listing System (FURLS)

1

The following required questions represent the information necessary to complete the PIA Summary for transmission to the Office of Management and Budget. Note: If a question or its response is not applicable, please answer "No" to that question.

2 Summary of PIA Required Questions

	Question	Response
1	System:	FDA OC FDA Unified Registration and Listing System (FURLS)
2	Is this a new PIA?	No
3	If this is an existing PIA, please provide a reason for revision:	Initial PIA Migration to ProSight
4	Date of this Submission:	Nov 20, 2003
5	OPDIV Name:	FDA
6	Unique Project Identifier (UPI) Number:	009-10-01-10-01-1030-00-114-043
7	Privacy Act System of Records (SOR) Number:	N/A
8	OMB Information Collection Approval Number:	0910-0502 10/31/2006
9	Other Identifying Number(s):	FDA Form Number 3537/3537a
10	System Name:	FDA Unified Registration and Listing System
11	System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:	FDA Privacy Act Officer
12	Provide an overview of the system:	On June 12, 2002, President Bush signed The Public Health Security and Bioterrorism Act of 2002 (PL 107-188). This Act was written to enhance the nation's ability to prevent, identify and respond to bioterrorism. In the case of FDA, the Bioterrorism Act substantially expands the authority the FDA can bring to bear in regulating the food industry. Domestic and foreign food facilities (importing food into the United States) will be required to register with FDA. Information required includes: name and address of facility; U.S. agent if foreign facility; and emergency contact information in the event of a public health emergency. As a result of this Act, FDA has a very aggressive schedule for rulemakings and systems addressing registration of food facilities, record-keeping and prior notice of imported food shipments. The Food Facility Registration System required in the Act will allow FDA to compile an up-to-date list of relevant facilities and to rapidly identify and contact potentially affected facilities in the context of possible bioterrorism involving the food supply. However, FDA must accommodate a registration period 60 days in advance of the statutory deadline of December 12, 2003 to assure that the international system of food production and transport is not disrupted. While FDA regulators work diligently to put the required regulations in place, the aggressive timeframe mandated under law applies also to the development of the Food Registration system. Therefore, the Food Facility Registration Module of the FDA Unified Registration and Listing System was brought on-line on October 16, 2003. Currently, approximately 4,000 registrations are completed per day through this system.
13	Indicate if the system is new or an existing one being modified:	Existing
14	Does/Will the system collect, maintain (store), disseminate and/or pass through IIF within any database(s), record(s), file(s) or website(s) hosted by this system?	No
15	Is the system subject to the Privacy Act?	No

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

HHS Privacy Impact Assessment (PIA) Summary

FDA: FDA OC FDA Unified Registration and Listing System (FURLS)

16	If the system shares or discloses IIF please specify with whom and for what purpose(s):	Per Sec. 1.243 (a) of the Final Interim Rule, the list of registered facilities and registration documents submitted under this subpart are not subject to disclosure. In addition, FDA does not disclose any information collected about facilities or facility contacts unless it is required by law or for law enforcement reasons. We only use facility identifying information to contact personnel in the facility in the event of an emergency of other regulatory need. FDA personnel involved in Food Registration, law enforcement or policy-making use the information provided. We may share this information with other government agencies that have public health or consumer protection duties such as the Department of Commerce.
17	Describe in detail the information the agency will collect, maintain, or disseminate and why and for what purpose the agency will use the information:	N/A
18	Describe the consent process:	N/A
19	Does the system host a website?	Yes
20	Does the website have any information or pages directed at children under the age of thirteen?	No
21	Are there policies or guidelines in place with regard to the retention and destruction of IIF?	No
22	Are there technical controls present?	Yes
23	Describe the IIF security controls:	N/A
24	Sr Official of Privacy Signature:	Kathleen D. Heuer
25	Sr Official of Privacy Signoff Date:	Jun 30, 2006

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

HHS Privacy Impact Assessment (PIA) Summary

FDA: FDA OC MDI Security System (MDI)

1

The following required questions represent the information necessary to complete the PIA Summary for transmission to the Office of Management and Budget. Note: If a question or its response is not applicable, please answer "No" to that question.

2 Summary of PIA Required Questions

	Question	Response
1	System:	FDA OC MDI Security System (MDI)
2	Is this a new PIA?	No
3	If this is an existing PIA, please provide a reason for revision:	Initial PIA Migration to ProSight
4	Date of this Submission:	Nov 24, 2003
5	OPDIV Name:	FDA
6	Unique Project Identifier (UPI) Number:	009-10-01-10-01-0308-00-401-121
7	Privacy Act System of Records (SOR) Number:	09-10-0018
8	OMB Information Collection Approval Number:	N/A
9	Other Identifying Number(s):	N/A
10	System Name:	FDA MDI Security System Network
11	System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:	FDA Privacy Act Officer
12	Provide an overview of the system:	The FDA MDI Security System Network is comprised of card access, intrusion alarms and maps and is utilized to provide FDA Identification/Access cards for FDA facilities. This information is provided pursuant to Public Law 93-597 (Privacy Act of 1974), December 31, 1974 for individuals applying for FDA Security Card Keys. Federal Property Management Regulations, 41 CFR 101.20.301, authorize the maintenance of systems by Government agencies for identifying individuals as employees in order to restrict access to Federal buildings after normal working hours and to areas not open to the general public.
13	Indicate if the system is new or an existing one being modified:	Existing
14	Does/Will the system collect, maintain (store), disseminate and/or pass through IIF within any database(s), record(s), file(s) or website(s) hosted by this system?	Yes
15	Is the system subject to the Privacy Act?	Yes
16	If the system shares or discloses IIF please specify with whom and for what purpose(s):	This information is collected to ensure that only authorized FDA employees, contractors, visiting scientists, etc. are issued FDA Identification/Access Badges.
17	Describe in detail the information the agency will collect, maintain, or disseminate and why and for what purpose the agency will use the information:	Employees' names, dates of birth, social security numbers, height, weight, vehicle tag number, access level, building, room number and whether they are a contractor, guest worker, visiting scientist, etc. are required before issuing an FDA Identification/Access Card which allows access to certain FDA facilities.
18	Describe the consent process:	Information is secured through different levels of passwords
19	Does the system host a website?	No
20	Does the website have any information or pages directed at children under the age of thirteen?	No
21	Are there policies or guidelines in place with regard to the retention and destruction of IIF?	No
22	Are there technical controls present?	Yes
23	Describe the IIF security controls:	This information is collected to ensure that only authorized FDA employees, contractors, visiting scientists, etc. are issued FDA Identification/Access Badges.
24	Sr Official of Privacy Signature:	Kathleen D. Heuer
25	Sr Official of Privacy Signoff Date:	Jun 30, 2006

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

HHS Privacy Impact Assessment (PIA) Summary

FDA: FDA OC PRISM Simplified Acquisition System (PRISM)

1

The following required questions represent the information necessary to complete the PIA Summary for transmission to the Office of Management and Budget. Note: If a question or its response is not applicable, please answer "No" to that question.

2 Summary of PIA Required Questions

	Question	Response
1	System:	FDA OC PRISM Simplified Acquisition System (PRISM)
2	Is this a new PIA?	No
3	If this is an existing PIA, please provide a reason for revision:	Initial PIA Migration to ProSight
4	Date of this Submission:	Nov 5, 2003
5	OPDIV Name:	FDA
6	Unique Project Identifier (UPI) Number:	009-10-01-10-01-0306-00-405-143
7	Privacy Act System of Records (SOR) Number:	N/A
8	OMB Information Collection Approval Number:	n/a
9	Other Identifying Number(s):	n/a
10	System Name:	PRISM
11	System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:	FDA Privacy Act Officer
12	Provide an overview of the system:	The Purchase Request Information System (PRISM) procurement information system is an automated system for electronic preparation, review/approval of requisitions and placement of procurement awards. PRISM automates the buying functions. PRISM streamlines, speeds and simplifies acquisition processes through parallel processing. Full Time Equivalent (FTE) personnel for creating and tracking procurement documentation are reduced through process automation. The Agency as a whole will benefit from this system due to increased efficiencies in the acquisition process and use of reporting tools.
13	Indicate if the system is new or an existing one being modified:	Existing
14	Does/Will the system collect, maintain (store), disseminate and/or pass through IIF within any database(s), record(s), file(s) or website(s) hosted by this system?	No
15	Is the system subject to the Privacy Act?	No
16	If the system shares or discloses IIF please specify with whom and for what purpose(s):	n/a
17	Describe in detail the information the agency will collect, maintain, or disseminate and why and for what purpose the agency will use the information:	For acquisitions, PRISM collects personally identifiable information about the names, office addresses, office telephone numbers and email addresses of federal employees. The records are of employees originating and approving purchase orders and delivery orders for FDA acquisitions. The federal employee information is collected at the time an acquisition order is originated or approved. The federal employee information is for system operation and federal procurement reporting requirements. Vendor names, telephone numbers, addresses, DUNS numbers, tax identification numbers and contacts information from the E-Government Central Contractor Registry System are also recorded in the PRISM database. The vendor information is for procurement award processing, vendor payment processing and federal reporting requirements. PRISM does not perform any other public or internal data collections.
18	Describe the consent process:	n/a
19	Does the system host a website?	No
20	Does the website have any information or pages directed at children under the age of thirteen?	No
21	Are there policies or guidelines in place with regard to the retention and destruction of IIF?	No
22	Are there technical controls present?	No
23	Describe the IIF security controls:	n/a
24	Sr Official of Privacy Signature:	Kathleen D. Heuer
25	Sr Official of Privacy Signoff Date:	Jun 30, 2006

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

HHS Privacy Impact Assessment (PIA) Summary

FDA: FDA OC Property Management System (ASSET)

1

The following required questions represent the information necessary to complete the PIA Summary for transmission to the Office of Management and Budget. Note: If a question or its response is not applicable, please answer "No" to that question.

2 Summary of PIA Required Questions

	Question	Response
1	System:	FDA OC Property Management System (ASSET)
2	Is this a new PIA?	No
3	If this is an existing PIA, please provide a reason for revision:	Initial PIA Migration to ProSight
4	Date of this Submission:	Oct 21, 2003
5	OPDIV Name:	FDA
6	Unique Project Identifier (UPI) Number:	009-10-01-10-01-0307-00-402-128
7	Privacy Act System of Records (SOR) Number:	N/A
8	OMB Information Collection Approval Number:	N/A
9	Other Identifying Number(s):	N/A
10	System Name:	Asset Management System (AMS)
11	System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:	FDA Privacy Act Officer
12	Provide an overview of the system:	The FDA Asset Management System (AMS) automates administrative management of accountable personal property equipment assets of the FDA throughout the life cycle from receipt to final disposition. Nearly all aspects of daily FDA business operations are supported by some form of accountable personal property equipment. A broad range of equipment items is managed in AMS, from testing devices to computer mainframes. Each asset item tracked in the system is a complete unit of equipment, durable in nature, with an expected service life of two or more years. Requirements for AMS are defined in the Joint Financial Management Improvement Program (JFMIP) document, JFMIP-SR-00-4, Federal Financial Management System Requirements, Property Management System Requirements issued in October 2002. A vast array of detailed information about assets users and contracts is required for effective property management. AMS provides a data repository of asset information as well as enabling asset security, inventorying, control, tracking, and movement. AMS is an internal effectiveness tool supporting Asset and Liability Management and Financial Management as specified in the Business Reference Model (v.2.0) of the Federal Enterprise Architecture.
13	Indicate if the system is new or an existing one being modified:	Existing
14	Does/Will the system collect, maintain (store), disseminate and/or pass through IIF within any database(s), record(s), file(s) or website(s) hosted by this system?	No
15	Is the system subject to the Privacy Act?	No
16	If the system shares or discloses IIF please specify with whom and for what purpose(s):	N/A
17	Describe in detail the information the agency will collect, maintain, or disseminate and why and for what purpose the agency will use the information:	Federal employee names and employee numbers are passed to the Asset Management System from another internal FDA administrative system, the Enterprise Administrative Support Environment (EASE). The information is transferred weekly and enables the assignment of responsible employee names and numbers to each item of FDA personal property entered in AMS. The information is needed in AMS for property searches in conjunction with periodic equipment inventories. The FDA Asset Management System does not perform any other public or internal personally identifiable information data collections.
18	Describe the consent process:	N/A
19	Does the system host a website?	No

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

HHS Privacy Impact Assessment (PIA) Summary

FDA: FDA OC Property Management System (ASSET)

20	Does the website have any information or pages directed at children under the age of thirteen?	No
21	Are there policies or guidelines in place with regard to the retention and destruction of IIF?	No
22	Are there technical controls present?	No
23	Describe the IIF security controls:	N/A
24	Sr Official of Privacy Signature:	Kathleen D. Heuer
25	Sr Official of Privacy Signoff Date:	Jun 30, 2006

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

HHS Privacy Impact Assessment (PIA) Summary

FDA: FDA OC Travel Manager (TM)

1

The following required questions represent the information necessary to complete the PIA Summary for transmission to the Office of Management and Budget. Note: If a question or its response is not applicable, please answer "No" to that question.

2 Summary of PIA Required Questions

	Question	Response
1	System:	FDA OC Travel Manager (TM)
2	Is this a new PIA?	No
3	If this is an existing PIA, please provide a reason for revision:	Initial PIA Migration to ProSight
4	Date of this Submission:	Nov 7, 2003
5	OPDIV Name:	FDA
6	Unique Project Identifier (UPI) Number:	009-10-01-01-01-2010-00-402-126
7	Privacy Act System of Records (SOR) Number:	09-90-0024
8	OMB Information Collection Approval Number:	N/A
9	Other Identifying Number(s):	N/A
10	System Name:	Travel Manager
11	System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:	FDA Privacy Act Officer
12	Provide an overview of the system:	Reengineering of the travel process has been a key priority for the Food and Drug Administration (FDA). Most agency travel processes were manual. Administrative staff reductions and increasing travel regulation complexity made automation a critical need. Improvements were further mandated by the Joint Financial Management Improvement Program (JFMIP) in issuance of Travel System Requirements, JFMIP-SR-99-9, dated July 1999. JFMIP is a cooperative undertaking of the U.S. Department of the Treasury, the General Accounting Office, the Office of Management and Budget, and the Office of Personnel Management. Travel Manager combines automated travel regulations, government forms generation and electronic document processing into a powerful, easy-to-use software service The system serves the travel needs of federal employees traveling on FDA business and non-employees sponsored for travel at FDA expense, e.g. invitational speakers, State or Local Government officials, investigators, regulators, etc. Only federal employees are provided direct access to TM. Non-employees traveling at FDA expense are categorized as Special Government Employees (SGE) and provided TM system support through a federal employee Document Preparer. In 2003, roughly one thousand or approximately 25% of FDA travelers were in the SGE category. TM has virtually eliminated FDA's manual administrative burden for both travel support and travel accounting with significant cost savings. TM is aligned with the Federal eTravel initiative for standardization and automation of travel processes.
13	Indicate if the system is new or an existing one being modified:	Existing
14	Does/Will the system collect, maintain (store), disseminate and/or pass through IIF within any database(s), record(s), file(s) or website(s) hosted by this system?	Yes
15	Is the system subject to the Privacy Act?	Yes

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

HHS Privacy Impact Assessment (PIA) Summary

FDA: FDA OC Travel Manager (TM)

16	If the system shares or discloses IIF please specify with whom and for what purpose(s):	Personally identifiable information about FDA Travelers in Travel Manager is collected using an internal Travel Manager Account Request/ Permission Rights Form. The form is completed by all system users before access to system capabilities are granted. The FDA Traveler name, social security number and other travel related profile information is used to process travel orders and generate electronic funds transfer reimbursements of travel expenses. Travel Manager does not perform any data collections unrelated to the processing of travel orders or reimbursements of travel expenses.
17	Describe in detail the information the agency will collect, maintain, or disseminate and why and for what purpose the agency will use the information:	Personally identifiable information about FDA Travelers in Travel Manager is collected using an internal Travel Manager Account Request/ Permission Rights Form. The form is completed by all system users before access to system capabilities are granted. The FDA Traveler name, social security number and other travel related profile information is used to process travel orders and generate electronic funds transfer reimbursements of travel expenses. Travel Manager does not perform any data collections unrelated to the processing of travel orders or reimbursements of travel expenses.
18	Describe the consent process:	Travel Manager collects information about FDA business travelers for purposes of processing travel orders, system operations and accounting operations associated with recording travel obligations and disbursements.
19	Does the system host a website?	Yes
20	Does the website have any information or pages directed at children under the age of thirteen?	No
21	Are there policies or guidelines in place with regard to the retention and destruction of IIF?	No
22	Are there technical controls present?	Yes
23	Describe the IIF security controls:	Travel Manager operates within the secure FDA computing environment. Access to the system is restricted to pre-authorized federal employees.
24	Sr Official of Privacy Signature:	Kathleen D. Heuer
25	Sr Official of Privacy Signoff Date:	Jun 30, 2006

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

HHS Privacy Impact Assessment (PIA) Summary

FDA: FDA OC User Fees

1

The following required questions represent the information necessary to complete the PIA Summary for transmission to the Office of Management and Budget. Note: If a question or its response is not applicable, please answer "No" to that question.

2 Summary of PIA Required Questions

	Question	Response
1	System:	FDA OC User Fees
2	Is this a new PIA?	No
3	If this is an existing PIA, please provide a reason for revision:	Initial PIA Migration to ProSight
4	Date of this Submission:	Jun 22, 2005
5	OPDIV Name:	FDA
6	Unique Project Identifier (UPI) Number:	009-10-01-01-01-4140-00-402-125
7	Privacy Act System of Records (SOR) Number:	N/A
8	OMB Information Collection Approval Number:	N/A
9	Other Identifying Number(s):	N/A
10	System Name:	User Fee System
11	System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:	FDA Privacy Act Officer
12	Provide an overview of the system:	The User Fee System is a component system of the Financial Enterprise Solutions (FES) Mission Critical computer security classification investment. The system application utilizes various modules of the Oracle eBusiness Suite, v.11.5.9. The system was developed to respond to the legislative needs of: Prescription Drug User Fee Act of 2003 Medical Device User Fee and Modernization Act of 2002 Animal Drug and User Fee Act of 2003 Mammography Quality Standards Act Internal users access the system through the firewall-shielded secure FDA network. Thousands of external industry users access the system via the Internet through a back and front-end, firewall-shielded sub-network in a demilitarized zone. System servers are located in the FDA Network Control Center on the second floor of the Parklawn building in Rockville, Maryland.
13	Indicate if the system is new or an existing one being modified:	Existing
14	Does/Will the system collect, maintain (store), disseminate and/or pass through IIF within any database(s), record(s), file(s) or website(s) hosted by this system?	No
15	Is the system subject to the Privacy Act?	No
16	If the system shares or discloses IIF please specify with whom and for what purpose(s):	N/A

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

HHS Privacy Impact Assessment (PIA) Summary

FDA: FDA OC User Fees

17	Describe in detail the information the agency will collect, maintain, or disseminate and why and for what purpose the agency will use the information:	The User Fee System collects data related to transactions for which external industry users must pay fees. Such transactions involve user fees associated with: · Prescription Drug User Fee Act of 2003 · Medical Device User Fee and Modernization Act of 2002 · Animal Drug and User Fee Act of 2003 · Mammography Quality Standards Act For internal federal users, the User Fee System collects specifically identifiable information about the names and email address. The records are of employees responsible for accessing Oracle Applications as approved by the account approval process. For external industry, the User Fee System collects business identifiable information about name, address, telephone numbers, email addresses, DUNS, waiver information and Federal Employee Identification number. All information collected is required to exchange by the federal government to facilitate payments required by the User Fee legislation. The data collected is the minimum necessary to complete the coversheet and billing processes.
18	Describe the consent process:	N/A
19	Does the system host a website?	No
20	Does the website have any information or pages directed at children under the age of thirteen?	No
21	Are there policies or guidelines in place with regard to the retention and destruction of IIF?	No
22	Are there technical controls present?	No
23	Describe the IIF security controls:	N/A
24	Sr Official of Privacy Signature:	Kathleen D. Heuer
25	Sr Official of Privacy Signoff Date:	Jun 30, 2006

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

HHS Privacy Impact Assessment (PIA) Summary

FDA: FDA ORA Automated Laboratory Management System (ALMS)

1

The following required questions represent the information necessary to complete the PIA Summary for transmission to the Office of Management and Budget. Note: If a question or its response is not applicable, please answer "No" to that question.

2 Summary of PIA Required Questions

	Question	Response
1	System:	FDA ORA Automated Laboratory Management System (ALMS)
2	Is this a new PIA?	No
3	If this is an existing PIA, please provide a reason for revision:	Initial PIA Migration to ProSight
4	Date of this Submission:	May 8, 2006
5	OPDIV Name:	FDA
6	Unique Project Identifier (UPI) Number:	009-10-01-02-02-1070-00-110-246 (FY08)
7	Privacy Act System of Records (SOR) Number:	N/A
8	OMB Information Collection Approval Number:	N/A
9	Other Identifying Number(s):	009-10-01-02-02-1070-00-110-246 (FY07 UPI)
10	System Name:	eLEXNET
11	System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:	FDA Privacy Act Officer
12	Provide an overview of the system:	The Electronic Laboratory Exchange Network (eLEXNET) was developed to facilitate secure information sharing among public health partners and collaboration among food safety experts. eLEXNET provides food safety officials with access to food test results for analytes of concern at the detail level and at the product or product industry level. eLEXNET is a seamless, integrated, secure network that provides multiple federal, state and local government agencies engaged in food safety activities with the ability to compare, communicate, and coordinate findings in laboratory analyses. The system enables U.S. health officials to assess risks, analyze trends and identify problem products. It provides the necessary infrastructure for an early-warning system that identifies potentially hazardous foods.
13	Indicate if the system is new or an existing one being modified:	Existing
14	Does/Will the system collect, maintain (store), disseminate and/or pass through IIF within any database(s), record(s), file(s) or website(s) hosted by this system?	No
15	Is the system subject to the Privacy Act?	No
16	If the system shares or discloses IIF please specify with whom and for what purpose(s):	N/A
17	Describe in detail the information the agency will collect, maintain, or disseminate and why and for what purpose the agency will use the information:	eLEXNET currently allows food safety laboratories at all levels of government (federal, state, local) to share real-time food safety sample and analysis data on selected microbiological analytes. eLEXNET receives sample status and sample analysis summary, laboratory analytical methods and results, and laboratory conclusions from other systems within FDA, as well as from participating laboratories. All data collections are necessary to meet the goals of this system. No Personally Identifiable Information is collected or stored in the eLEXNET system. Prior to obtaining access credentials, when laboratories agree with and sign the written Memorandum of Understanding (MOU), they are informed of the data collection process
18	Describe the consent process:	N/A
19	Does the system host a website?	Yes
20	Does the website have any information or pages directed at children under the age of thirteen?	No
21	Are there policies or guidelines in place with regard to the retention and destruction of IIF?	No
22	Are there technical controls present?	No
23	Describe the IIF security controls:	N/A
24	Sr Official of Privacy Signature:	Kathleen D. Heuer
25	Sr Official of Privacy Signoff Date:	Jun 30, 2006

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

HHS Privacy Impact Assessment (PIA) Summary

FDA: FDA ORA Field Accomplishments and Compliance Tracking System (FACTS)

1

The following required questions represent the information necessary to complete the PIA Summary for transmission to the Office of Management and Budget. Note: If a question or its response is not applicable, please answer "No" to that question.

2 Summary of PIA Required Questions

	Question	Response
1	System:	FDA ORA Field Accomplishments and Compliance Tracking System (FACTS)
2	Is this a new PIA?	No
3	If this is an existing PIA, please provide a reason for revision:	Initial PIA Migration to ProSight
4	Date of this Submission:	May 12, 2006
5	OPDIV Name:	FDA
6	Unique Project Identifier (UPI) Number:	009-10-01-08-01-1010-00-110-032
7	Privacy Act System of Records (SOR) Number:	N/A
8	OMB Information Collection Approval Number:	N/A
9	Other Identifying Number(s):	N/A
10	System Name:	Field Accomplishments and Compliance Tracking System (FACTS)/Electronic State Access to FACTS (eSAF)
11	System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:	FDA Privacy Act Officer
12	Provide an overview of the system:	FDA's inspection process, managed by FACTS, is responsible for the health and safety of the American Public by providing support to the overall FDA's mission for promoting and protecting the public health by helping safe and effective products reach the market, and monitoring products for continued safety after they are in use. Legislation authorizing this activity is the Food Drug and Cosmetic Act.
13	Indicate if the system is new or an existing one being modified:	Existing
14	Does/Will the system collect, maintain (store), disseminate and/or pass through IIF within any database(s), record(s), file(s) or website(s) hosted by this system?	No
15	Is the system subject to the Privacy Act?	No
16	If the system shares or discloses IIF please specify with whom and for what purpose(s):	No

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

HHS Privacy Impact Assessment (PIA) Summary

FDA: FDA ORA Field Accomplishments and Compliance Tracking System (FACTS)

17	Describe in detail the information the agency will collect, maintain, or disseminate and why and for what purpose the agency will use the information:	The FACTS system contains data about commercial firms and their business relationships, data, FDA decisions, manpower, procedures, establishments, commerce, compliance, enforcements, products, consumer complaints and FDA organizations. The FACTS database provides information on FDA performance to Congress and the OMB, and supports the Drug industry's PDUFA initiatives. This system also presents rapid review of current and past fieldwork assignments, results, and time/cost to accomplish in the Agency mission areas of regulation, surveillance, and compliance. Providing support to the overall FDA's mission for promoting and protecting the public health by helping safe and effective products reach the market, and monitoring products for continued safety after they are in use. FACTS shares collected information with the following systems: Lab data exchange between FACTS-OASIS (ORA), Data to FACTS Reports; OPAS (ORA), Assignment data to Turbo EIR (ORA), Firm profile data to ORA/DCIQA (Intranet/Internet), Lab data to eLEXNET (ORA, CFSAN), Complaints & Adverse event data to CAERS (CFSAN), Firm profile data feed to CDER, Pre-approval inspection data exchange with EES (CDER), Firm data to eDRLS (CDER), Inspection data from MPRIS & CASS (CDRH) The primary users of FACTS are FDA organizations (see above) that enter, update, retrieve, and otherwise manipulate the data contained in the FACTS database with the ORA Field Offices staff being the principal suppliers of FACTS data. The Centers then make extensive use of FACTS to communicate with the Field. The secondary users of FACTS include organizations and individuals' external to the FDA that contributes industry information to the FACTS database. These include consumers, health care providers, state partners, state public health agencies, and other Federal agencies FACTS has built-in controls to grant or modify access to the relevant data based on the user role and District he or she belongs to with FACTS end users having only 'read only' access to data from other district offices. For the FACTS/eSAF system there are three primary security zones. The three zones are 1) the Internet, 2) the Service Area Network, or Demilitarized Zone (DMZ), and 3) the Intranet or "inner core". This approach separates the functions of "border control," "identification and authentication," and "access control."
18	Describe the consent process:	N/A
19	Does the system host a website?	No
20	Does the website have any information or pages directed at children under the age of thirteen?	No
21	Are there policies or guidelines in place with regard to the retention and destruction of IIF?	No
22	Are there technical controls present?	Yes
23	Describe the IIF security controls:	N/A
24	Sr Official of Privacy Signature:	Kathleen D. Heuer
25	Sr Official of Privacy Signoff Date:	Jun 30, 2006

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

HHS Privacy Impact Assessment (PIA) Summary

FDA: FDA ORA On-line Program Analysis System (OPAS)

1

The following required questions represent the information necessary to complete the PIA Summary for transmission to the Office of Management and Budget. Note: If a question or its response is not applicable, please answer "No" to that question.

2 Summary of PIA Required Questions

	Question	Response
1	System:	FDA ORA On-line Program Analysis System (OPAS)
2	Is this a new PIA?	No
3	If this is an existing PIA, please provide a reason for revision:	Initial PIA Migration to ProSight
4	Date of this Submission:	May 10, 2006
5	OPDIV Name:	FDA
6	Unique Project Identifier (UPI) Number:	009-10-01-08-01-0201-00-301-092
7	Privacy Act System of Records (SOR) Number:	N/A
8	OMB Information Collection Approval Number:	N/A
9	Other Identifying Number(s):	N/A
10	System Name:	Online Program Analysis System
11	System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:	FDA Privacy Act Officer
12	Provide an overview of the system:	OPAS extracts employee accomplishment information from the ORA Field Accomplishments and Compliance Tracking System (FACTS). The extracted information refers to the employees' work activities by Operation, Firm, Location, Position Class, Program Code, and Number of Hours. This employee information is then counted and aggregated for each dimension (Operation, Location, Position Class, Program Code, Fiscal Year). Values are loaded into an Oracle Express multi-dimensional database for display to the OPAS users (Headquarters managers and analysts, and field managers). Work plan information is collected from the MODEL files, but MODEL stores no data for an individual employee. In the future, MODEL will be replaced with Field Workforce Planning System (FWFPS). OPAS does not display public information (i.e., names of Firms). Although this information is collected through FACTS, OPAS displays only counts of Firms in various categories (by Establishment Type, Industry Code, Location, and Fiscal Year)
13	Indicate if the system is new or an existing one being modified:	Existing
14	Does/Will the system collect, maintain (store), disseminate and/or pass through IIF within any database(s), record(s), file(s) or website(s) hosted by this system?	No
15	Is the system subject to the Privacy Act?	No
16	If the system shares or discloses IIF please specify with whom and for what purpose(s):	N/A
17	Describe in detail the information the agency will collect, maintain, or disseminate and why and for what purpose the agency will use the information:	N/A
18	Describe the consent process:	N/A
19	Does the system host a website?	No
20	Does the website have any information or pages directed at children under the age of thirteen?	No
21	Are there policies or guidelines in place with regard to the retention and destruction of IIF?	No
22	Are there technical controls present?	No
23	Describe the IIF security controls:	N/A
24	Sr Official of Privacy Signature:	Kathleen D. Heuer
25	Sr Official of Privacy Signoff Date:	Jun 30, 2006

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

HHS Privacy Impact Assessment (PIA) Summary

FDA: FDA ORA Operating and Admin. Sys. Import Support (OASIS)

1

The following required questions represent the information necessary to complete the PIA Summary for transmission to the Office of Management and Budget. Note: If a question or its response is not applicable, please answer "No" to that question.

2 Summary of PIA Required Questions

	Question	Response
1	System:	FDA ORA Operating and Admin. Sys. Import Support (OASIS)
2	Is this a new PIA?	No
3	If this is an existing PIA, please provide a reason for revision:	Initial PIA Migration to ProSight
4	Date of this Submission:	Nov 26, 2003
5	OPDIV Name:	FDA
6	Unique Project Identifier (UPI) Number:	009-10-01-08-01-1020-00-110-032
7	Privacy Act System of Records (SOR) Number:	N/A
8	OMB Information Collection Approval Number:	N/A
9	Other Identifying Number(s):	N/A
10	System Name:	Operational & Admin. System for Import Support (OASIS)
11	System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:	FDA Privacy Act Officer
12	Provide an overview of the system:	OASIS automated the re-engineered business processes the FDA utilizes for making its admissibility determinations to ensure the safety, efficacy and quality of the foreign-origin products for which FDA has regulatory responsibility under the Federal Food, Drug and Cosmetic Act.
13	Indicate if the system is new or an existing one being modified:	Existing
14	Does/Will the system collect, maintain (store), disseminate and/or pass through IIF within any database(s), record(s), file(s) or website(s) hosted by this system?	No
15	Is the system subject to the Privacy Act?	No
16	If the system shares or discloses IIF please specify with whom and for what purpose(s):	N/A

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

HHS Privacy Impact Assessment (PIA) Summary

FDA: FDA ORA Operating and Admin. Sys. Import Support (OASIS)

17	Describe in detail the information the agency will collect, maintain, or disseminate and why and for what purpose the agency will use the information:	The information is collected initially from the Customs and Border Protection through their ACS system. All time spent reviewing commercial entry data, both on-screen and via paper entry documentation, are recorded as Entry Review. This includes checking regulatory status by accessing Center databases or FIARS, review of FD Form 2877s, Affirmation of Compliance Codes and their qualifiers, and review for data accuracy during Entry Review. In addition, all time spent to make and record May Proceed decisions, regulatory recommendations such as Detention Requests (DTR) or Detention w/o Exam Requests (DER) and setting up Investigations exam/collect work assignments should be recorded as Entry Review. Any changes to transmitted data found to be inaccurate are made before setting up exam/sample assignments if possible. Such errors are then provided to the district personnel responsible for conducting filer evaluations. In summary OASIS is a mission critical system that supports about 3500 FDA users throughout the US users on a 24/7 basis. It provides: o An automated interface with US Customs Service systems o Automated pre-screening processes o Support for Entry-Reviewers and Compliance Officer review of regulated products, including computer-aided decision-making o Maintenance of information for reporting decision-making o Tracking and review of workflow The OASIS information is shared with Dept. of Homeland Security, Customs and Border Protection (ACS), FACTS, ORADSS, and FDA Centers. OASIS enables FDA to handle more efficiently and effectively the burgeoning volume of shipments (now over 8 million/year -- up by 50% in the last four years) of imported products, despite decreasing agency resources. Maximize the efficiency and accuracy of the import review process to ensure the safety of imports regulated by FDA on behalf of the American public. OASIS automates a number of previously manual processes, provides more timely data and better data integrity to support decision-making. It also provides supports better workflow between the Entry Reviewers and Compliance Officers as well as an ability to monitor performance. No, IIF information is being collected.
18	Describe the consent process:	N/A
19	Does the system host a website?	No
20	Does the website have any information or pages directed at children under the age of thirteen?	No
21	Are there policies or guidelines in place with regard to the retention and destruction of IIF?	No
22	Are there technical controls present?	No
23	Describe the IIF security controls:	N/A
24	Sr Official of Privacy Signature:	Kathleen D. Heuer
25	Sr Official of Privacy Signoff Date:	Jun 30, 2006

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

HHS Privacy Impact Assessment (PIA) Summary

FDA: FDA ORA ORADSS

1

The following required questions represent the information necessary to complete the PIA Summary for transmission to the Office of Management and Budget. Note: If a question or its response is not applicable, please answer "No" to that question.

2 Summary of PIA Required Questions

	Question	Response
1	System:	FDA ORA ORADSS
2	Is this a new PIA?	No
3	If this is an existing PIA, please provide a reason for revision:	Initial PIA Migration to ProSight
4	Date of this Submission:	May 12, 2006
5	OPDIV Name:	FDA
6	Unique Project Identifier (UPI) Number:	009-10-01-02-01-1040-00-111-033
7	Privacy Act System of Records (SOR) Number:	N/A
8	OMB Information Collection Approval Number:	N/A
9	Other Identifying Number(s):	N/A
10	System Name:	ORADSS
11	System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:	FDA Privacy Act Officer
12	Provide an overview of the system:	This is a data warehouse and reporting system developed to provide domestic and import reports to headquarters and field users.
13	Indicate if the system is new or an existing one being modified:	Existing
14	Does/Will the system collect, maintain (store), disseminate and/or pass through IIF within any database(s), record(s), file(s) or website(s) hosted by this system?	No
15	Is the system subject to the Privacy Act?	No
16	If the system shares or discloses IIF please specify with whom and for what purpose(s):	Not Applicable
17	Describe in detail the information the agency will collect, maintain, or disseminate and why and for what purpose the agency will use the information:	The information available in this system can be broken down into different areas. 1. Data that is collected as a result of a product being imported into this country. Basically the type of product and how it is packaged. 2. Data that is collected as a result of sample collections. The data collected includes data such as pac, product, industry, firm name, hours, and operation date. 3. Data that is collected as a result of firm inspections. The data collected includes data such as pac, product, industry, firm name, hours, and operation date. 4. Data that is collected as a result of sample analysis. The data collected includes data such as pac, product, industry, firm name, hours, operation date, and results. 5. Data that is collected as a result of legal actions taken against a firm. The history of the legal action is recorded such as when an action was proposed, when it was sent to legal council, etc.
18	Describe the consent process:	We don't keep any personal data on individuals.
19	Does the system host a website?	No
20	Does the website have any information or pages directed at children under the age of thirteen?	No
21	Are there policies or guidelines in place with regard to the retention and destruction of IIF?	No
22	Are there technical controls present?	No
23	Describe the IIF security controls:	Not Applicable
24	Sr Official of Privacy Signature:	Kathleen D. Heuer
25	Sr Official of Privacy Signoff Date:	Jun 30, 2006

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

HHS Privacy Impact Assessment (PIA) Summary

FDA: FDA ORA Recall Enterprise System (RES)

1

The following required questions represent the information necessary to complete the PIA Summary for transmission to the Office of Management and Budget. Note: If a question or its response is not applicable, please answer "No" to that question.

2 Summary of PIA Required Questions

	Question	Response
1	System:	FDA ORA Recall Enterprise System (RES)
2	Is this a new PIA?	No
3	If this is an existing PIA, please provide a reason for revision:	Initial PIA Migration to ProSight
4	Date of this Submission:	Nov 12, 2003
5	OPDIV Name:	FDA
6	Unique Project Identifier (UPI) Number:	009-10-01-08-01-1011-00-110-032
7	Privacy Act System of Records (SOR) Number:	N/A
8	OMB Information Collection Approval Number:	N/A
9	Other Identifying Number(s):	N/A
10	System Name:	MARCS Recalls (Recall Enterprise System - RES)
11	System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:	FDA Privacy Act Officer

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

FDA: FDA ORA Recall Enterprise System (RES)

12	Provide an overview of the system:	The MARCS Recalls system provides centralized and standard safety and health alerts and regulated product recall information both internally at the FDA and externally to the public (MARCS Recalls Internet – see comments below with regard to the availability of the Internet application). Alerts and recalls are an effective method of providing alert notices to the public, and removing or correcting consumer products that are in violation of the laws administered by the FDA. The MARCS Recalls Intranet system is FDA's first agency wide Recall IT system. MARCS Recalls supports business processes for managed application reviews, workload management, investigative, compliance, and analytical operations, quality assurance and other critical initiatives (Manage and Conduct Compliance Work; Monitor Recall; Monitor Regulatory Actions; Negotiate Compliance Action; Support Regulatory Field Action; View Firm Information). MARCS Recalls Intranet allows FDA personnel to create recall alerts, document recall actions, and to recommend a recall strategy. The system provides capabilities to close recalls when completed and to archive/retain recall records for future use. The system also provides a capability to post a subset of the recall information to the Internet (MARCS Recalls Internet) allowing the general public to view recall information. Although the posting of the data to the Internet database is active, this is currently not available for public access. The MARCS Recalls Intranet application provides automated support for the daily operations of ORA Field Offices and Headquarters to support the compliance and enforcement activities of FDA's office of Regulatory Affairs(ORA). MARCS Recalls Intranet is an online system that also integrates with other strategic systems at the FDA to provide additional support and information for the recall. MARCS Recalls Intranet system integrates with the "FIRMS" data (holds shared information for the (Field Accomplishment and Compliance Tracking System (FACTS); Operation Administrative System for Import Services (OASIS)), as read only, and allows for information to be stored with the recall record. MARCS Recalls Intranet also allows for a precedent search for (CDRH) recalls requiring Health Hazard Evaluation (HHE) information. The MARCS Recalls Intranet supports approximately 50 to 100 concurrent users (per day). MARCS Recalls Intranet has approximately 512 FDA Intranet users that are recorded in the application users, across the U.S. The FDA's Office of Regulatory Affairs (ORA) is focused on assuring that manufacturing firms comply with FDA regulations in order to achieve consumer safety and health protection. The FDA's Investigations Operations Manual 2003 states that "ORA's mission is to achieve effective and efficient compliance of regulated products through high quality, science-based work that results in maximizing consumer protection." Within ORA, the Recall Operations Staff (ROS) in the Office of Enforcement (OE), Division of Compliance Management and Operations (DCMO) serves as the Agency's focal point for all safety and health alerts, and product recall activities. ROS is also responsible for providing policy, procedure, and direction to the FDA field and Center recall operations as dictated by the Food, Drug and Cosmetic (FD&C) Act.
13	Indicate if the system is new or an existing one being modified:	Existing
14	Does/Will the system collect, maintain (store), disseminate and/or pass through IIF within any database(s), record(s), file(s) or website(s) hosted by this system?	No
15	Is the system subject to the Privacy Act?	No
16	If the system shares or discloses IIF please specify with whom and for what purpose(s):	N/A

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

HHS Privacy Impact Assessment (PIA) Summary

FDA: FDA ORA Recall Enterprise System (RES)

17	Describe in detail the information the agency will collect, maintain, or disseminate and why and for what purpose the agency will use the information:	Almost all of the data captured through the RES application is non-personal and can be grouped into the follow categories: · Firm information · Product information · Center-specific information · Recall Event information · Recall Recommendation information · Recall Classification information · Recall Summary and Termination information Personally Identifiable Information (PII) is limited to the minimum amount needed for effective communication in the system. This communication has two aspects, internal and external. The internal aspect of the system uses the names and email addresses of the individual FDA employees who create or work with the records in the RES application. These needed pieces of PII, the employee's name and email address, come from the FDA's FACTS database, which is accessed through the individual's RES login codes. The user's name and email provides access to the user's profile information record in the RES database. These records contain information regarding each user's role, and the FDA Center with responsibility for the over sight of the recall activity. In addition to FDA employees, pieces of PII are also capture in regards to the reporting company, the name(s) of the company point(s) of contact, their email addresses, and company mailing addresses. These pieces of information are provided to FDA by the reporting company(s) for means of communication. The External use of PII is that the company involved in the recall provides the name and email address of a company representative so the public can make enquiries regarding the recall.
18	Describe the consent process:	N/A - no IIF
19	Does the system host a website?	Yes
20	Does the website have any information or pages directed at children under the age of thirteen?	No
21	Are there policies or guidelines in place with regard to the retention and destruction of IIF?	No
22	Are there technical controls present?	No
23	Describe the IIF security controls:	N/A - no IIF
24	Sr Official of Privacy Signature:	Kathleen D. Heuer
25	Sr Official of Privacy Signoff Date:	Jun 30, 2006

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

HHS Privacy Impact Assessment (PIA) Summary

FDA: FDA ORA TurboEIR (Turbo)

1

The following required questions represent the information necessary to complete the PIA Summary for transmission to the Office of Management and Budget. Note: If a question or its response is not applicable, please answer "No" to that question.

2 Summary of PIA Required Questions

	Question	Response
1	System:	FDA ORA TurboEIR (Turbo)
2	Is this a new PIA?	No
3	If this is an existing PIA, please provide a reason for revision:	Initial PIA Migration to ProSight
4	Date of this Submission:	May 12, 2006
5	OPDIV Name:	FDA
6	Unique Project Identifier (UPI) Number:	009-10-01-08-01-1060-00-110-032
7	Privacy Act System of Records (SOR) Number:	09-10-0002
8	OMB Information Collection Approval Number:	N/A
9	Other Identifying Number(s):	(FY 2007 UPI) 009-10-01-02-02-1060-00-110-246
10	System Name:	FDA Turbo EIR
11	System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:	FDA Privacy Act Officer
12	Provide an overview of the system:	The Turbo EIR Field Agent application provides a standardized database of citations, and assists the investigator in preparation of the FDA Form 483 and the Establishment Inspection Report (EIR). FDA field investigators annually conduct approximately 17,000 establishment inspections. A Food Drug and Cosmetic Act requirement of the inspectional process is to report (in writing) certain types of adverse observations to the management of the inspected firm at the conclusion of the inspection. About forty percent of all inspections result in the issuance of an FDA 483. The FDA 483 is the written report listing the adverse observations observed by the investigator. The investigators must also generate a comprehensive narrative for each inspection. These narratives are known as Establishment Inspection Reports (EIRs) and are commonly prepared with word processing software. Turbo EIR Field Agent provides onscreen guidance to the investigator for preparation of the EIR. Turbo on the Web is a web browser based application that allows FDA users to retrieve FDA 483 and EIR documents via the FDA intranet.
13	Indicate if the system is new or an existing one being modified:	Existing
14	Does/Will the system collect, maintain (store), disseminate and/or pass through IIF within any database(s), record(s), file(s) or website(s) hosted by this system?	No
15	Is the system subject to the Privacy Act?	No
16	If the system shares or discloses IIF please specify with whom and for what purpose(s):	The information is shared with various compliance/management operational divisions (such as Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research, Center for Food Safety and Applied Nutrition, Center for Devices and Radiological Health, Center for Veterinary Medicine) in the FDA that perform enforcement, analysis and trending.

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

HHS Privacy Impact Assessment (PIA) Summary

FDA: FDA ORA TurboEIR (Turbo)

17	Describe in detail the information the agency will collect, maintain, or disseminate and why and for what purpose the agency will use the information:	Turbo EIR Field Agent gathers data on the specific violations observed during the inspection and proceedings that transpire during the course of the inspection. Those data (and the FDA 483 items themselves) are then uploaded to a central database where they are available in the FDA for analysis and trending. The EIRs are also available online. The standardization inherent in Turbo EIR reduces inconsistency and lack of uniformity in the FDA 483 process. Specific personally identifiable information collected by Turbo EIR is names of establishment employees that participated in the FDA inspection. The collection of these names is to identify the most responsible person at the establishment and to note how establishment employees participated in the conduct of the inspection. These names are not used by the Turbo EIR system for data searches. The information is provided voluntarily.
18	Describe the consent process:	Assigned an inspection, the investigator travels to the establishment to perform it. If the investigator observes adverse conditions they are linked to the FDA citation database in Turbo EIR Field Agent. Within Turbo EIR Field Agent the investigator is then able to provide specific information relating to each observation. When all observations and specifics are recorded Turbo EIR Field Agent prints the FDA 483. The investigator then meets with the management of the firm and explains the adverse observations recorded. At this point the firm's management has an opportunity to have their comments added to the FDA 483. At the end of the management meeting the investigator presents the final FDA 483 (with comments) to the firm's management and the inspection is complete. Afterwards the investigator using Turbo EIR Field Agent authors the Establish Inspection Report (EIR). An EIR is created for each inspection, even if a FDA 483 is not issued. The EIR is a comprehensive report of the inspection and contains information needed to support the Violation Letter process and of interest to FDA management.
19	Does the system host a website?	Yes
20	Does the website have any information or pages directed at children under the age of thirteen?	No
21	Are there policies or guidelines in place with regard to the retention and destruction of IIF?	Yes
22	Are there technical controls present?	No
23	Describe the IIF security controls:	The controls to secure information collected by Turbo EIR Field Agent are strong encryption techniques both locally and in the establishment of connections, access controls on the system and on the network where the system resides, detection and auditing of unauthorized access attempts and data verification routines.
24	Sr Official of Privacy Signature:	Kathleen D. Heuer
25	Sr Official of Privacy Signoff Date:	Jun 30, 2006

Note on IIF: Any question about IIF seeks to identify any, and all, personal information associated with the system. This includes any IIF, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Note: If no IIF is contained in the system, please answer the remaining required questions, then promote the PIA to the Sr. Privacy Official who will authorize the PIA. Note: If this system contains IIF, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.